

Claims 1-3, 7-13, 16-19, 23-24 and 27-31 were rejected in the Office Action under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent Application Publication No. US 2002/0138143 A1 to Grooms *et al.* ("Grooms"). The Office Action stated:

Grooms *et al.* discloses a cortical bone cervical fusion implant with all the elements of claims 1, 16 and 27. See Figure 8A and paragraphs [0010], [0018], [0024] and [0049] for bone fusion implant (800) comprising a hollow body with a completely enclosed hollow region (when fragments are connected) formed between at least two bone fragments (801A, 801B) which are configured and dimensioned for mutual engagement and which are coupled together.

(Office Action, Page 3, lines 22-26).

Applicants' invention, as presented in independent claim 1, is directed to a bone fusion implant for repair or replacement of bone comprising a hollow body with a substantially enclosed hollow region formed between at least two bone fragments which are configured and dimensioned for mutual engagement and which are coupled together.

Applicants' invention, as presented in independent claim 16, is directed to a bone fusion implant for repair or replacement of bone comprising a hollow body formed from at least two bone fragments which are configured and dimensioned for mutual engagement and which are coupled together, wherein the hollow body further comprises a completely enclosed hollow region.

Applicants' invention, as presented in independent claim 27, is directed to a bone fusion implant for repair or replacement of bone comprising: a substantially enclosed hollow interior space formed between at least two bone fragments which are configured and dimensioned for mutual engagement and which are coupled together; and an outer surface conforming in shape with the end plates of vertebrae and having at least one migration resistant feature thereon.

Grooms is directed to a cortical bone cervical Smith-Robinson fusion implant. As disclosed in Fig. 8A of Grooms, implant 800 is composed of two side-by-side halves, 801A and 801B, that together form a "D"-shaped profile. According to Grooms, the two halves of the implant are brought into juxtaposition to form a unitary implant. (Grooms, Paragraph 49, lines 3-6). A "D"-shaped internal canal may be provided, for example, to permit a purchase (a "key way") within the implant for external machining of the implant. (*Id.*, Paragraph 37, 14-21). As shown in Fig. 4A of Grooms, the spindle 420 of a lathe 400 may be accommodated in the "D"-shaped keyway. (*See, e.g.*, Grooms, Paragraph 42). However, Grooms is understood to be silent with respect to a substantially enclosed hollow

region or interior space, or a completely enclosed hollow region. Applicants submit that the “D”-shaped implant of Grooms is open-ended.

With respect to claims 2-3, 7-13 and 24 which depend from independent claim 1, claims 17-19 and 23 which depend from claim 16, and claims 28-31 which depend from claim 27, it is submitted that these claims are patentable not only because of the patentability of the independent claim from which they depend, but also for the totality of features recited respectively therein.

Claims 4-6, 14-15, 20-21 and 32-33 were rejected in the Office Action under 35 U.S.C. § 103(a) as being unpatentable over Grooms in view of U.S. Patent No. 6,123,731 to Boyce *et al.* (“Boyce”). The rejection is respectfully traversed.

As noted with respect to the previous rejection under Section 102, Grooms discloses an open-ended construction. Grooms is understood to be silent with respect to a substantially enclosed hollow region or interior space, or a completely enclosed hollow region. Boyce is directed to an osteoimplant and method for its production, and discloses that “[t]he osteoimplant can possess one or more cavities which, if desired, can communicate with the surface of the implant through pores, apertures, perforations or channels provided for this purpose.” (Boyce, Col. 4, lines 51-54). Boyce further discloses that “[a] cavity can be formed by removing bone material with, for example, a drill, or, alternatively, a cavity can be formed by assembling appropriately configured layers of bone-derived elements.” (*Id.*, Col. 8, lines 7-10). However, Boyce also is understood to be silent with respect to a substantially enclosed hollow region or interior space, or a completely enclosed hollow region. Grooms and Boyce therefore are insufficient, both alone as well as in combination, to render claims 4-6, 14-15, 20-21 and 32-33 obvious. Moreover, because claims 4-6, 14-15, 20-21 and 32-33 ultimately depend from independent claims that have been shown above to be allowable, claims 4-6, 14-15, 20-21 and 32-33 also should be allowable.

Claims 22, 26 and 34 were rejected in the Office Action under 35 U.S.C. § 103(a) as being unpatentable over Grooms in view of U.S. Patent No. 5,989,289 to Coates *et al.* (“Coates”). The Office Action stated that “Grooms *et al.* discloses a cortical bone cervical fusion implant with all the elements of claims 1, 16 and 27, but is silent to the implant comprising a region sized to receive a surgical instrument, as required by claims 22, 26 and 34.” The Office Action further stated that “[i]t would have been obvious to one of ordinary skill in the art to modify the implant of Grooms *et al.* to include a region sized to receive a surgical instrument, as taught by Coates *et al.*, in order for a surgeon to be able to use a tool in implanting the fusion implant.” The rejection is respectfully traversed.

Again, as noted with respect to the previous rejection under Section 102, Grooms discloses an open-ended construction. Grooms is understood to be silent with respect to a substantially enclosed hollow region or interior space, or a completely enclosed hollow region. Coates is directed to bone grafts, for example in the form of a D-shaped spacer 110. The open-ended construction of Coates thus is also understood to be silent with respect to a substantially enclosed hollow region or interior space, or a completely enclosed hollow region. Grooms and Coates therefore are insufficient, both alone as well as in combination, to render claims 22, 26 and 34 obvious. Moreover, because claims 22, 26 and 34 ultimately depend from independent claims that have been shown above to be allowable, claims 22, 26 and 34 also should be allowable.

Claim 25 was rejected in the Office Action under 35 U.S.C. § 103(a) as being unpatentable over Grooms in view of U.S. Patent No. 5,895,426 to Scarborough *et al.* ("Scarborough"). The rejection is respectfully traversed.

As noted with respect to the previous rejection under Section 102, Grooms discloses an open-ended construction. Grooms is understood to be silent with respect to a substantially enclosed hollow region or interior space, or a completely enclosed hollow region. Coates is directed to a fusion implant device and method of use, and is also understood to be silent with respect to the construction recited in independent claim 1, from which claim 25 depends. Grooms and Coates therefore are insufficient, both alone as well as in combination, to render claim 25 obvious. Moreover, because claim 25 ultimately depends from an independent claim that has been shown above to be allowable, claim 25 also should be allowable.

In view of the foregoing, it is believed that all the pending claims are in condition for allowance, which is respectfully requested. If the Examiner does not agree, then a personal or telephonic interview is respectfully requested to discuss any remaining issues and accelerate the eventual allowance of the claims.

A fee for an extension of time is believed to be due for this submission and a petition for extension of time is submitted concurrently herewith. Should any additional fees be required, please charge such fees to Pennie & Edmonds LLP Deposit Account No. 16-1150.

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Respectfully Submitted,

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Enclosure